



Atty. Dkt. No. 066683-0190

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Tomoki TODO et al.  
Title: USE OF SOLUBLE COSTIMULATORY FACTOR  
FOR TUMOR IMMUNO-GENE THERAPY  
Appl. No.: 09/679,147  
Filing Date: 10/05/2000  
Examiner: Anne Marie Sabrina Wehbe  
Art Unit: 1632

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(c), before the mailing date of either a final action under 37 CFR §1.113, a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application.

12/05/2003 SHINASS1 00000048 09679147

01 FC:1806

180.00 0P

**RELEVANCE OF EACH DOCUMENT**

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

**FEE**

A fee in connection with submission of an information disclosure statement under 37 CFR §1.97(c) in the amount of \$180.00 in accordance with 37 CFR §1.17(p) is attached.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date December 4, 2003

FOLEY & LARDNER  
Washington Harbour  
3000 K Street, N.W., Suite 500  
Washington, D.C. 20007-5143  
Telephone: (202) 672-5300  
Facsimile: (202) 672-5399



---

Matthew E. Mulkeen  
Registration No. 44,250

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

Date Submitted: December 4, 2003

(Use as many sheets as necessary)

Sheet 1 of 1

**Complete if Known**

Application Number	09/679,147
Filing Date	10/05/2000
First Named Inventor	Tomoki TODO
Group Art Unit	1632
Examiner Name	Anne Marie Sabrina Wehbe
Attorney Docket Number	066683-0190

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A1	KOBY et al., "Oncolytic viral therapy for human colorectal cancer and liver metastases using a multi-mutated herpes simplex virus type-1 (G207)," The FASEB Journal, Vol. 13, August 1999, pp. 1325-1334	
	A2	WALKER et al., "Local and Systemic Therapy of Human Prostate Adenocarcinoma with Conditionally Replicating Herpes Simplex Virus Vector G207," Human Gene Therapy, Vol. 10, September 1, 1999, pp. 2237-2243	
	A3	Oyama et al., "Intravesical and Intravenous Therapy of Human Bladder Cancer by the Herpes Vector G207," Human Gene Therapy, Vol. 11, August 10, 2000, pp. 1683-1693	
	A4	CAREW et al., "Selective Infection and Cytolysis of Human Head and Neck Squamous Cell Carcinoma with Sparing of Normal Mucosa by a Cytotoxic Herpes Simplex Virus Type 1 (G207), Human Gene Therapy, Vol. 10, July 1, 1999, pp. 1599-1606	
	A5	DELMAN et al., "Effects of Preexisting Immunity on the Response to Herpes Simplex-Based Oncolytic Viral Therapy, Human Gene Therapy, Vol. 11, December 10, 2000, pp. 2465-2472	
	A6	BENNETT et al., "Antitumor efficacy of regional oncolytic viral therapy for peritoneally disseminated cancer," J. Mol. Med, Vol. 78, 2000, pp. 166-174	
	A7	COZZI et al., "Intravesical oncolytic viral therapy using attenuated, replication-competent, herpes simplex viruses G207 and Nv1020 is effective in the treatment of bladder cancer in an orthotopic syngeneic model," The FASEB Journal, express article 10.1096/fj. 00-0533 fje, published on line march 5, 2001.	
	A8	EBRIGHT et al., "Replication-competent herpes virus NV1020 as direct treatment of pleural cancer in a rat model," The Journal of Thoracic and Cardiovascular Surgery, Vol. 1124, 2002, Number 1	

 Examiner  
Signature

 Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.